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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/308,219	09/19/1994	MARC ALIZON	3495.001020	4832

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/308,219	Applicant(s) ALIZON ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

The double patenting rejections are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region of HIV ORF-R are presented below.

```
Alignment

Query:                                          gacagggcttggaaaggattttgctataaga 8153
                                                ||||||||||||||||||||||||||||||
Sbjct:                                          gacagggcttggaaaggattttgctataaga 8354


Query: 8154 tgggtggcaagtggtcaaaaagtagtgtggttggatggcctgctgtaagggaaagaatga 8213
            ||||||||||||||||||||||||||||||||||||||||||| ||||||||||||||||
Sbjct: 8355 tgggtggcaagtggtcaaaaagtagtgtggttggatggcctactgtaagggaaagaatga 8414
orfF   11   M  G  G  K  W  S  K  S  S  V  V  G  W  P  T  V  R  E  R  M


Query: 8214 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273
            ||||||||||||||||||||||||||||||||||||||||||||||||||||| |||||||||||
Sbjct: 8415 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatg 8474
orfF   31   R  R  A  E  P  A  A  D  G  V  G  A  A  S  R  D  L  E  K  H


Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333
            |||||||||||||||||| |||||||||| |||||||| ||||||||||||||||||||
Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534
orfF   51   G  A  I  T  S  S  N  T  A  A  T  N  A  A  C  A  W  L  E  A
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```
Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393
            ||||||||||||||||||||||||| ||||||||||||||||||||||||||||||||
Sbjct: 8535 aagaggaggaggaggtgggttttccactcacacctcaggtacctttaagaccaatgactt 8594
orfF   71   Q  E  E  E  E  V  G  F  P  L  T  P  Q  V  P  L  R  P  M  T

Query: 8394 acaaggcagctgtagatcttagccacttttaaaagaaaaggggggactggaagggctaa 8453
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 8595 acaaggcagctgtagatcttagccacttttaaaagaaaaggggggactggaagggctaa 8654
orfF   91   Y  K  A  A  V  D  L  S  H  F  L  K  E  K  G  G  L  E  G  L

Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
orfF   111  I  H  S  Q  R  R  Q  D  I  L  D  L  W  I  Y  H  T  Q  G  Y

Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573
            ||||||||| |||||||||||||||||||||| |||||||||||||||||||||||||
Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774
orfF   131  F  P  D  W  Q  N  Y  T  P  G  P  G  V  R  Y  P  L  T  F  G

Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633
            |||||||||||||||||||||||||||||| ||| ||||||| ||||| ||||||||||
Sbjct: 8775 ggtgctacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834
orfF   151  W  C  Y  K  L  V  P  V  E  P  D  K  V  E  E  A  N  K  G  E

Query: 8634 acaccagcttgttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693
            |||||||||||||||||||||||||||||||||||||||||||||| ||||||||||||
Sbjct: 8835 acaccagcttgttacaccctgtgagcctgcatggaatggatgaccctgagagagaagtgt 8894
orfF   171  N  T  S  L  L  H  P  V  S  L  H  G  M  D  D  P  E  R  E  V

Query: 8694 tagagtggaggtttgacagccgcctagcatttcatcacatggcccgagagctgcatccgg 8753
            |||||||||||||||||||||||||||||||||||| ||||||||||||||||||||
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcatcacgtggcccgagagctgcatccgg 8954
orfF   191  L  E  W  R  F  D  S  R  L  A  F  H  H  V  A  R  E  L  H  P

Query: 8754 agtacttcaagaactgc
            |||||||||||||||||
Sbjct: 8955 agtacttcaagaactgc
orfF   211  E  Y  F  K  N  C
```

It is noted that with regard to, for example, the sequence region of ORF-R claimed in claim 15, there are 14 nucleotide differences between the sequences. It is

noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 657 nucleotide sequence which is the sequence of claim 13, 14 errors would represent approximately a 2.1% error rate. Thus, these sequences are identical within the error range available and the inherency issue is proper.

Chang does not specifically select the sequence of claim 15. However, Chang expressly suggests selection of sequences for diagnostic purposes as well as for expression purposes. The sequence of claim 15 represents the

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make utilize this sequence since it is a functional equivalent open reading frame which an ordinary practitioner would have been motivated to select for use as a diagnostic probe and for use in studying the pathology of the HIV virus.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

> "Normally, a *prima facie* case of obviousness is based upon structural similiarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs

> because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed sequence simply represents a structural homolog, which are derived from sequences suggested by the Chang prior art as useful for primers and probes for the detection of HIV and for expression of HIV open reading frames, and in particular for expression of HIV proteins, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claim 15 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claim 15 as discussed above.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Change because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological

specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

Response to Arguments

5. Applicant's arguments filed November 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that limiting the claim to consisting of overcomes the Chang rejection under 102. This argument is correct. However, the limitation does not overcome the 103 rejection because selection of a particular nucleic acid sequence from a larger nucleic acid sequence, where there is a motivation to select the sequence, and the selected sequence meets the criteria set out by the prior art reference, here the Chang reference, is prima facie obvious. Chang wished to select all of the ORF sequences in HIV-1. This is one of the ORF sequences and the no secondary consideration regarding the specific length chosen has been provided. Evidence of a secondary consideration can overcome this prima facie case of obviousness.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

December 19, 2002